

PFS analysis of BOLERO-2 trial. Afterwards, we fitted parametric models to the reconstructed IPD in the statistical package Stata. Both statistical and graphical tests were conducted to verify the relative and absolute validity of the findings. Finally, the equations for transition probabilities were derived using the general equation for transition probabilities used in model-based economic evaluations, and the parameters were estimated from fitted distributions. **RESULTS:** The results of the application of the tutorial suggest that the log-logistic model best fits the reconstructed data from the latest published KM curves of the BOLERO-2 trial. Results from the regression analyses were confirmed graphically. An equation for transition probabilities was obtained for each arm of the BOLERO-2 trial. **CONCLUSIONS:** In this paper, a tutorial was proposed and used to estimate the transition probabilities for model-based economic evaluation, based on the results of the final PFS analysis of the BOLERO-2 trial in mBC. These results can serve as a basis for any model (Markov) that needs the parameterization of transition probabilities, and only has summary Kaplan-Meier plots available.

PRM74

THE INHERENT BIAS FROM USING PARTITIONED SURVIVAL MODELS IN ECONOMIC EVALUATION

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OBJECTIVES: Increasingly, economic evaluations of progressive diseases have adopted the approach of partitioned survival analysis. In three state cancer models (pre-progression, post-progression and death) the proportion of patients in each state are often obtained from survival functions for progression free (PFS) and overall survival (OS). The proportion in the pre-progression state is estimated from the PFS curve and the proportion in the post-progression state is the difference between OS and PFS. Based on simulated data reflecting the results from recent randomized clinical trials, this study explored the accuracy of this method. **METHODS:** Three clinical scenarios were considered based on varying OS. Clinical trial data sets were simulated for a standard and a novel treatment assuming substantive benefit with the new treatment in terms of slowing progression but no impact of treatment on mortality rates within health states. Costs and utility values for each state were assumed and represent plausible values. Analysis identified the difference between actual results based on complete follow up and results based on curtailed follow up of various durations using both traditional Markov modelling and partitioned survival analysis. **RESULTS:** In the moderate survival scenario (median OS ~12 months), the ICUR for the new treatment based on the raw simulated data was \$119,600. With trial follow up of 9 months the ICUR for new treatment was \$120,600 with Markov modelling and \$87,500 with partitioned survival analysis. With 18 months follow up, the figures were \$122,500 and \$103,000 respectively. Results with different durations of follow up found a consistent pattern as did results for both the short and long term survival scenarios. **CONCLUSIONS:** Analyses based on partitioned survival analysis have an inherent bias in favour of treatments which impact disease progression, not within health state mortality. They should not be considered an appropriate basis to facilitate reimbursement decisions.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PRM75

PSYCHOMETRIC VALIDATION OF PATIENT-REPORTED OUTCOME MEASURES OF PAIN IN UNITED STATES PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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OBJECTIVES: This study evaluated the psychometric properties of the Brief Pain Inventory-Short Form (BPI-SF) in patients with moderate-to-severe systemic lupus erythematosus (SLE). **METHODS:** Participants were recruited using a free electronic medication-monitoring service. Patients ≥ 18 years who self-reported a physician diagnosis of SLE (confirmed by medical record review) and active SLE demonstrated by a Systemic Lupus Activity Questionnaire (SLAQ) score of ≥ 11 (0-44 scale) were included. BPI-SF and SF-36 were administered in electronic format at baseline, week 2, and week 12. Psychometric properties of the BPI-SF and items and domains were evaluated by standard statistical techniques. **RESULTS:** A total of 122 patients were included. Cronbach's alpha were >0.9 for all BPI-SF items. Test-retest reliability of the BPI-SF showed a stable correlation for item #7 (Intraclass Correlation Coefficient 0.79); all other items and domain correlations were >0.5 . The BPI-SF domain and global scores were moderately positively correlated to the SLAQ score (all correlations $r > 0.4$), but negatively correlated to the SF-36 Bodily Pain domain ($r < -0.6$). The BPI-SF domain and global scores were moderately negatively correlated to the SF-36 Physical Function domain and Physical Component scores, with low correlations between the pain severity domain and SF-36 Mental Component scores ($r = -0.16$). The BPI-SF item #3 (worst pain) was moderately positively correlated to the SLAQ score ($r = 0.49$). Patients who self-reported inactive or less active disease activity (SLAQ < 29) scored lower on domain and global scores ($p < 0.05$) and item #3 ($p < 0.0001$), compared to patients who self-reported active disease activity (SLAQ ≥ 29). The findings suggested all BPI-SF domain scores and item #3 were able to differentiate between patients with less severe or more severe pain. **CONCLUSIONS:** Assessment of pain intensity, as measured by the BPI-SF, demonstrated validity and reliability in a sample of patients with SLE and may be used as a patient-reported outcome tool in clinical trials.

PRM76

PSYCHOMETRIC PROPERTIES OF THE WORLD HEALTH ORGANIZATION'S QUALITY OF LIFE-BREF INSTRUMENT (WHOQOL-BREF) AMONG ADULTS WITH AUTISM

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OBJECTIVES: The purpose of this study was to assess construct validity of the World Health Organization's Quality of Life-BREF (WHOQOL-BREF) instrument among adults with autism. Reliability and floor and ceiling effects of the WHOQOL-BREF instrument in this population were also assessed. **METHODS:** A cross-sectional online survey (using Qualtrics survey system) of adults with autism enrolled with the Interactive Autism Network (IAN) was performed for study purposes. Among adults with autism registered with the IAN, those aged 18 years and above and having the capacity to self-report with little or no proxy help were identified and targeted for the study. The proposed structure of the WHOQOL-BREF instrument was validated using confirmatory factor analysis. Convergent and discriminant validity was assessed based on relevant item-total correlation. Known-groups validity was tested by comparing WHOQOL-BREF scores among group differing in autism severity. Cronbach's alpha was used to assess internal consistency reliability. Floor and ceiling effects were determined based on percentage ($\geq 15\%$) of responses with lowest and highest possible score on the instrument, respectively. **RESULTS:** The final sample included 262 adults with autism. Based on the CFA analysis, the second-order hierarchical model of WHOQOL-BREF instrument was considered the best fitting model among adults with autism (chi-square=428.00, df=242; RMSEA=0.054; CFI=0.091). Corrected item-total correlation suggested good convergent and discriminant validity of the WHOQOL-BREF instrument. Scores for the physical and psychological domains of the WHOQOL-BREF varied significantly by autism severity, indicating adequate known-groups validity. High internal consistency reliability (Cronbach's alpha 0.914) was observed. The floor and ceiling effect are acceptable with the exception of one item which displayed floor effect and six items which displayed ceiling effects. **CONCLUSIONS:** Study results indicated that the WHOQOL-BREF is a psychometrically sound instrument to assess quality of life among adults with autism.

PRM77

DO EQ-5D AND SF-6D ASK THE RIGHT QUESTIONS IN MENTAL HEALTH? A CONTENT VALIDATION USING INTERVIEWS WITH PATIENTS

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OBJECTIVES: The objective was to examine the content of EQ-5D and SF-6D against what individuals with mental health problems perceive to be important to their quality of life using rigorous qualitative methods. **METHODS:** We first undertook a systematic review of qualitative research undertaken with people with mental health problems. This review provided the basis for the topic guide used in semi structured in-depth interviews undertaken with 19 people who had a broad range of mental health problems at varying levels of severity drawn from primary and secondary care services (including mood disorders and psychosis) in the UK. The interviews were analysed thematically using framework analysis. **RESULTS:** A framework analysis of 13 qualitative studies revealed six major themes: well-being and ill-being; control, autonomy and choice; self-perception; belonging; activity; and hope. Despite widening the types and severity of mental health problems studied, our interview data fitted well with the themes from the review, any differences tended to be within the themes and related to the degree of impact of the themes on different levels of severity, chronicity and diagnosis. Physical health was also found to be more important amongst the interviewees, so it was added as a seventh theme as opposed to a minor sub-theme in the review. **CONCLUSIONS:** The review of qualitative research and our own interviews raises important questions about the content validity of the EQ-5D and SF-6D in mental health. While well-being and ill-being are partly covered by dimensions like 'depression and anxiety' and 'feeling downhearted and low', this leaves out other important aspects such as control, autonomy and choice; self-perception; belonging (to society); and hope.

PRM78

A COMPARISON OF THE UTILITY OF VARIANTS OF THE CHARLSON COMORBIDITY INDEX (CCI) IN PREDICTING PATIENT-REPORTED HEALTH OUTCOMES

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OBJECTIVES: The Charlson Comorbidity Index (CCI), although intended to predict mortality risk, is widely used as a means of controlling for comorbidities. Charlson et al. (2008; CCI2008) added items to better predict resource use and alternatively Quan et al. (2011; CCI2011) removed or updated the weighting of comorbidities to reflect modern estimates of contributions to mortality risk. The current study assessed the predictive utility of these three CCI variants across categories of health outcomes. **METHODS:** Data were analyzed from the 2013 U.S. National Health and Wellness Survey (n=75,000), an annual, cross-sectional, general health survey of adults (aged ≥ 18). CCI scores were calculated from a weighted sum of self-reported diagnoses. Health outcomes included: health-related quality of life measured via the SF-36v2 (mental and physical health status, and health utilities); Work Productivity and Activity Impairment (WPAI-GH) questionnaire-based measures; and resource use (visits to the emergency room, hospital, and traditional providers in the last 6 months). CCI scores were correlated with health outcomes (Pearson correlations for HRQoL, Spearman's rho for WPAI-GH and resource use). **RESULTS:** All correlations were significant, $p < .001$, with higher CCI scores associated with worse outcomes. CCI, CCI2008, and CCI2011 correlations ranged from lows of -.06, -.20, and -.07, respectively (with mental health status), to -.34, -.37, and -.30 (with physical health status), .27, .36, and .24 (with activity impairment), and .33, .39, and .25 (with provider visits). **CONCLUSIONS:** Across all outcomes, CCI2008 exhibited the strongest correlations, with the original CCI exhibiting slightly higher correlations than CCI2011 in all but two cases. The utility of the CCI depends on variance explained in the outcomes plus the anticipated independence of included comorbidities vis-à-vis predictors of interest in multivariable models.

PRM79

SYSTEMATIC REVIEW OF THE Q-TWIST IN ONCOLOGY

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